

**TRADITIONAL MEDICINE USE IN PATIENTS ON ANTIRETROVIRAL
THERAPY: A CROSS-SECTIONAL STUDY AT THEMBALETHU
WELLNESS CENTRE, NORTHDAL HOSPITAL**

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Master of Public Health in the School of Nursing and Public Health

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ABSTRACT

Introduction

Adherence is the primary predictor of treatment success with antiretroviral therapy (ART). It is not known whether the use of traditional medicine use predicts non-adherence to ART. Traditional medicine use has been reported to be common among individuals with moderate and advanced HIV disease. There is some data available on the prevalence and patterns of African Traditional Medicine (ATM) use in patients with HIV/ AIDS.

Aim

The aim of this cross-sectional study was to describe the prevalence of traditional medicine use amongst patients on antiretroviral therapy, aged 18-49 years and to assess any association between the use of traditional medicines and adherence to antiretroviral therapy in patients seen at Themba lethu Wellness Centre, Northdale Hospital, in KwaZulu-Natal, South Africa.

Methods

Using systematic sampling, 75 HIV-positive patients on antiretroviral therapy were selected from the pharmacy queue. Data was collected using primarily a semi-structured questionnaire with closed and open-ended questions during a face-to-face interview. The questionnaire was translated to Zulu. Pre-testing of the questionnaire was completed with 5 HIV-infected persons not involved in the study from another hospital. Data from closed-ended questions was collected, coded and captured on computer using the Microsoft Excel spreadsheet programme then all data was imported to SPSS programme for analysis.

Results

The study findings showed that, of the seven individuals who reported using traditional medicines, three (42.9%) also reported to have missed ART doses with one who reported missing more than three doses in the preceding month. Traditional medicines were mostly used by African men who followed Christian religion.

Traditional medicines were mainly used for cultural purposes specifically; cleansing purposes for different reasons. Male sex and the use of African traditional medicines were shown to be associated with poor adherence to antiretroviral therapy.

Conclusion

Although many previous studies have shown that traditional medicines were commonly used concomitantly with antiretroviral drugs by HIV positive patients; in this study only 9.3% of participants admitted having used traditional medicines in the 28 days preceding the survey. Participants were more likely to be non-adherent to ART if they were male and self-reported using traditional medicine.

PLAGIARISM DECLARATION

This Master of Public Health dissertation is my own work and all primary and secondary sources have been appropriately acknowledged. The dissertation has not been submitted to any other institution as part of an academic qualification.

This Dissertation is prepared in partial fulfillment of the requirement of the degree of Master of Public Health at the School of Nursing and Public Health, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa.

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DEDICATION

I dedicate this dissertation to the following people:

- The study participants who volunteered to participate in the study. Thank you for your contribution to the health care of South Africa.
- My family who gave me support throughout the study.

ACRONYMS AND ABBREVIATIONS

ATM	: African Traditional Medicine
HIV	: Human immunodeficiency virus infection
AIDS	: Acquired immunodeficiency syndrome
HAART	: Highly Active Antiretroviral Therapy
ART	: Antiretroviral Therapy
ARV	: Antiretroviral
NNRTI	: Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	: Nucleoside Reverse Transcriptase Inhibitor
PI	: Protease Inhibitor
PLWH	: People Living With HIV
TCAM	: Traditional, complementary or alternative medicine
CAT	: Complementary, Alternative and Traditional
WHO	: World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Introduction

South Africa (SA) has one of the highest incidences of HIV/AIDS in the world, and has implemented a number of initiatives to combat the pandemic. One of these is to roll out antiretroviral therapy (ART) through its public health facilities, which is provided free of charge at most clinics. However, while it is believed that many of those living with HIV also rely on African traditional healers as part of their overall health-seeking behavior, there is little empirical evidence to suggest to what extent this occurs in those on ART, and how this affects adherence to ART. In particular, it is not known whether the use of traditional medicine use predicts non-adherence to ART. Such information could inform interventions to enhance adherence counseling and strengthen the health care system's response to the AIDS pandemic.

As a pharmacist, one of my responsibilities is to ensure safe and optimal use of medication therefore this study is relevant to my profession because anything that may hinder efficacy of medication such as drug-drug interactions and non-adherence to medication needs to be addressed. Pharmacists have played a key role in combating the HIV/AIDS epidemic, being the interface between ART prescriptions and patient access, their role being to dispense medication and provide information about medication. Their knowledge of medicines formulations makes them key players in the health care team. They contribute by monitoring adherence to treatment and the emergence of management of adverse effects of the medications they dispense. A pharmacist is often the person that patients approach for advice and with whom they discuss their experiences with adverse effects. It is therefore important for pharmacists to understand the factors that affect patient adherence. Their knowledge about medicines formulations can assist in understanding the complications associated with the use of other remedies, such as traditional medicines.

In an era when people across the globe are seeking health through traditional, complementary or alternative medicines, often due to perceived or actual safety problems with “orthodox” medicines, greater attention needs to be paid to the consequences of the use of such remedies.

This Chapter presents the background to the study, specifically outlining the historical background of HIV in SA, and how the epidemic has progressed over the years. It also discusses the introduction of ART, the impact that delayed access to ART had in SA, and the eventual development of what has become the largest ART programme of any country. It briefly touches on concomitant use of ART and traditional medicine and further explains the rationale behind doing this study elaborating on its background, aim and objectives.

1.2 Background

The early phase of the HIV epidemic in SA was similar to that experienced elsewhere, with the initial cases identified in men who have sex with men. After the first case of HIV in SA was reported in 1982, prevalence of HIV infection in the general heterosexual population remained relatively low at least until 1987 (Abdool Karim and Abdool Karim, 2002). In the late 1980s and early 1990s, HIV and AIDS made its way onto the national health agenda. Based on annual anonymous antenatal surveys, national HIV prevalence rates rose from 0.76% in 1990 to 10.44% in 1995 and 22.4% in 2000 (Department of Health, 2001).

Anonymous HIV sero-prevalence surveys, conducted among people who attended a prenatal clinic in the Hlabisa district of KwaZulu-Natal province, showed a rise in prevalence from 4.2% in 1992 to 34.0% in 1999 (Abdool Karim and Abdool Karim, 2002). Incidence rose from 2.3 per 100 person-years in 1993 to 15.0 per 100 person-years in 1999. It was estimated that, in 2000, 40% of all adult deaths in SA were due to AIDS. The increased deaths in younger persons were clearly demonstrated by the change in the ratio of the number of deaths in those aged 15-49 years to the number of deaths in those aged over 50 years, between 1990 and 1999/2000.

In males, the ratio increased from 0.66 to 1.00; whereas in females it increased from 0.31 to 0.78 (Abdool Karim and Abdool Karim, 2002). The South African Health Review 2014/15 reported that the total number of patients on ART in the public sector exceeded 3 million in April 2015, up from 2.6 million in April 2014. However, the National Strategic Plan (NSP) Review raised some serious concerns (NSP, 2012-2016): it noted that between 2014 and 2015 the number of people on ART grew by 150 000 in Gauteng, but by only 6 000 in North West, 17 000 in the Free State and 40 000 in Mpumalanga (Day and Gray, 2015).

South Africa has made great progress in tackling its HIV epidemic during the presidency of Jacob Zuma, who was appointed in 2009. The NSP 2007-2011 saw a dramatic scaling-up of South Africa's ART programme. The HIV and AIDS programme grew significantly since 2010/11, and had been accompanied by a reduction in child mortality rates. Reduction in mother-to-child HIV transmission was noted from 35 percent to 2.5 percent, increased antiretroviral treatment coverage by an average of 500 000 new patients per year, lowered adult mortality rates, an increased number of medical male circumcisions, and the maintenance of HIV testing at high rates (National Strategic Plan 2014/15-2018/19). In 2011, the UNAIDS World AIDS Day Report stated that the sub-Saharan African region had the highest incidence of HIV/AIDS, with approximately 68% of those living with HIV at that time being from this region, which represented only 12% of the global population (UNAIDS, 2011). The region also accounted for 70% of new HIV infections in 2010, although there was a notable decline in the regional rate of new infections. The epidemic continues to be most severe in southern Africa, with South Africa having more people living with HIV (an estimated 5.6 million) than any other country in the world. Hughes *et al.* (2012) reported that there were approximately 20.8 million individuals in sub-Saharan Africa living with HIV. The total number of persons living with HIV in SA increased from an estimated 4 million in 2002 to 5.26 million by 2013 (NDOH, 2014).

1.2.1 Availability of Antiretroviral Therapy

The first antiretroviral (ARV) medicine made available to treat HIV in South Africa was zidovudine (variably abbreviated as either ZDV or AZT), which became available in 1998. When it was reported that a trial using a short course of ZDV in Thailand had reduced the mother-to-child transmission (MTCT) rate by half, this led advocates and researchers in South Africa to call for access to such preventive methods (Ijumba *et al.*, 2003). A far simpler approach, peri-natal provision of nevirapine (NVP), took center stage in the debate on access, which was driven mainly by the Treatment Action Campaign (TAC), from 1998 to 2001 (Ijumba *et al.*, 2003).

On 19 April 2001, there was a dramatic turn in the legal challenge faced by Nelson Mandela and his government against lawyers acting for South Africa's Pharmaceutical Manufacturers' Association (PMA), which represented 40 multinational pharmaceutical companies in the Pretoria High Court. PMA's lawyers had informed the judge that it was unconditionally withdrawing its case against the country's government and that it would bear all costs in the matter (Mbali, 2013). The Mandela administration was then free to implement the Medicines and Related Substances Amendment Act (Act 90 of 1997), in order to enable wider access to cheaper generic and imported patented drugs. Moreover, this successful campaign against the court case had a meaningful impact for poor patients in developing countries and successfully altered the politics of ARV pricing globally. Under voluntary licensing provisions, or in countries where patents were either not in place or not enforced, improved access to lower-priced generic ARVs facilitated a significant widening of global access to this treatment. This was particularly notable in sub-Saharan Africa, after the creation of new financing mechanisms such as the Global Fund to Fight AIDS, TB and Malaria (GFATM) and the US President's Emergency Fund for AIDS relief (PEPFAR). In addition, the pharmaceutical industry introduced substantial reductions in the prices of certain branded ARVs in some settings (Mbali, 2013).

Since 2004, ARVs have been made available at South Africa public health facilities at no charge for those living with HIV who met eligibility criteria.

Over time the CD4 threshold for eligibility to ART has been increased from 200 per ml, to 350, and now to 500 (NDOH, 2014). The most recent of these changes was made by the Minister of Health, Dr. Aaron Motsoaledi, during his budget speech in July 2014. A move to a test-and-treat approach, removing the CD4 threshold is widely expected, in line with the most recent World Health Organization guidelines (WHO, 2013).

UNAIDS (2014) reported that 2.3 million people gained access to ART in 2013, which would bring the global number of people accessing ART to nearly 13 million. While UNAIDS projected that by July 2014 as many as 13 950 296 people would be able to access ART, the report further showed that 19 million of the 35 million people living with HIV did not know that they were infected. UNAIDS further reported that research showed that in sub-Saharan Africa 76% of people on ART have achieved viral suppression, and were unlikely to transmit the virus to their sexual partners (UNAIDS, 2014). As of June 2015, 15.8 million people living with HIV were accessing ART, up from 13.6 million in June 2014. By the end of 2014, 36.9 million people globally were living with HIV, 2 million people became newly infected with HIV and 1.2 million people died from AIDS-related illnesses (UNAIDS, 2015). UNAIDS further reported that 41% of all adults living with HIV were accessing treatment in 2014, up from 23% in 2010. However, only 32% of all children living with HIV were accessing treatment in 2014, up from 14% in 2010. In 2014, 73% of pregnant women living with HIV had access to ARVs to prevent transmission of HIV to their babies and new HIV infections among children were reduced by 58% between 2000 and 2014.

It cannot be over-emphasized that correct adherence to ART is essential for good treatment outcomes, as it can prevent both the emergence of drug resistance and continued immunosuppression (Naidoo *et al.*, 2013).

1.2.2 Global use of traditional medicine

In some Asian and African countries, it has been claimed that as many as 80% of the population depend on traditional medicine for primary health care (WHO, 2008).

In addition the WHO (2008) reported that, in many developed countries, surveys have shown that 70% to 80% of the population have used some form of alternative or complementary medicine. Herbal medicines were the most popular form of traditional medicine, and form a highly lucrative part of the international market for such products. Annual revenues in Western Europe reached US\$5 billion in 2003-2004. In China, sales of Traditional Chinese Medicine (TCM) products totalled US\$14 billion in 2007 (WHO, 2008).

1.2.3 National use of traditional medicine

The extent of traditional medicines use in South Africa has not been well characterised, particularly in patients living with HIV. There are some data available on the extent of reliance on traditional healers as the first point of call for households experiencing illness or injury, from each edition of the Statistics South Africa General Household Survey (Statistics South Africa, 2015), but these are not specific to the population living with HIV. In the General Household Surveys, the percentage of households that would first consult a traditional healer has consistently been very low, below 1%. That may be an under-estimate of the extent of use of traditional medicines. Studies undertaken outside South Africa have reported that between 15% and 79% of people living with HIV utilise traditional medicine, representing a higher rate of utilisation than that shown in people with other serious illnesses (Puoane *et al.*, 2012).

1.2.4 Concomitant use of Antiretroviral Therapy and African Traditional Medicine

A review of reports on the use of African Traditional Medicine amongst people living with HIV, showed that there was evidence to suggest concomitant use of ARVs and traditional remedies, and that the reasons for such use included perceived alignment with cultural and/ or religious beliefs, use as a safe alternative to ARVs, for synergism with ARVs, to alleviate the adverse effects of ARVs, as a general way to promote health and quality of life and to treat HIV-related fatigue, nausea and pain (Muller and Kanfer, 2011). However, very few patients informed their health care providers of their use of traditional medicines or their reasons for using such products.

Malangu (2007) reported that approximately 75% of HIV-infected patients in South Africa also took some form of complementary or ATM at the same time. Mudzviti *et al.* (2012) reported that the majority of patients (98%) in their study, which was conducted at a Family Care Centre ART clinic in Zimbabwe, were taking at least one indigenous herbal remedy together with their ART regimen.

In South Africa, it was claimed that 80-90% of Black African patients use both the traditional healers and the biomedical personnel's services out of the need for the best healing therapy to fulfill their health needs (Pinkoane *et al.*, 2012). However; in a study conducted in Pretoria on self-reported use of traditional medicines by patients on ART, only 8.9% reported using a limited range of over-the-counter products as well as those from traditional medicine practices (Malangu, 2007).

The studies by both Pinkoane *et al.* (2012) and Mudzviti *et al.* (2012) showed results that were almost similar, but the results provided by Malangu (2007) are quite different. This supports the need to further examine the extent of use of ATM in patients receiving ART in South Africa.

1.2.5 National Policy and Regulation for African Traditional Medicine

Regulating traditional medicine products, practices and practitioners is difficult due to variations in definitions and categorisations of traditional medicine therapies. A single herbal product could be defined as food, a dietary supplement or herbal medicine, depending on the country. This disparity in regulations at the national level has implications for international access and distribution of product (WHO, 2008). In a briefing held by South African Department of Health on 'Institutionalisation of the Use of Traditional Medicine', it was mentioned that the Medicines Control Council (MCC) had established an African Traditional Medicines Committee to evaluate traditional medicines, with a view to facilitating their registration. In that briefing an African medicine clinical trials committee was also announced, to develop guidelines for managing such clinical trials (Minister of Health, 2008). A ministerial task team would investigate the functioning of these bodies with a view to improving their efficiency and relevance.

A Draft National Policy on African Traditional Medicine in South Africa has been issued, and is designed to provide a framework for the institutionalization of African Traditional Medicine in the South African system (Minister of Health, 2008).

In May 2014, the President issued a promulgation notice bringing some sections of the Traditional Health Practitioners Act (Act 22 of 2007) into operation (Gray and Vawda, 2015). Progress in this regard had been slow as the planned Traditional Health Practitioners Council faced serious challenges, to initial set-up funding, also in relation to contacting and recording the large number of traditional health practitioners of various categories who were already in practice (Gray and Vawda, 2015).

1.3 Problem Statement

Despite the effectiveness of ART being documented and having changed the progression of the disease in South Africa, many people in the country, and other developing countries, also seek treatment from traditional healers. The extent of use of ATM in patients on ART is not well documented, and there is inconclusive evidence on how its concurrent use impacts on adherence to ART. This information is important, as a lack of adherence has implications for the ongoing effectiveness of the medication as well as the wellbeing of those who do not take it regularly.

1.4 Research Question

What is the prevalence of ATM use among patients on ART at the Thembaletu Wellness Centre, Northdale Hospital, and is there any association between the use of ATM and adherence to ART.

1.5 Aim and Objectives

The broad aim of this study is to contribute to the understanding of the delivery of ART in an African setting, and thus to the development of appropriate interventions aimed at maximizing the benefits of such therapy.

The study had the following objectives:

1. To describe the prevalence of ATM use in study participants on ART provided by Northdale Hospital.
2. To identify which ATMs are most commonly used by study participants on ART.
3. To describe the study participants' perceptions about the effectiveness and safety of ATMs in this setting.
4. To investigate factors associated with the use of ATMs by study participants on ART.
5. To compare the level of adherence to ART amongst users and non-users of ATMs, as recorded by the Northdale ARV pharmacy.
6. To make recommendations on appropriate patient care; including advice on the concurrent use of ATMs by those on ART.

1.6 Definition of terms

Non-adherence: as missing three or more doses of antiretroviral treatment in a period of one month.

Traditional medicine: According to WHO, traditional medicine includes “diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness” (WHO, 2002).

African traditional medicine: a locally developed definition is that “in South Africa, most people associate traditional medicine with the herbs, remedies (or *muthi*) and advice imparted by *isangoma* or *izinyanga*— traditional healers from African indigenous groups – and with strong spiritual components” (Richter, 2003).

Antiretroviral therapy (ART): these are used to treat infection by retroviruses, primarily HIV. Therapy with antiretroviral medicines constitutes ART. When several such medicines, typically three, are taken in combination, the approach is known as highly active antiretroviral therapy (HAART) or combination ART (cART).

1.7 Study Outline

The study is presented in the following five chapters:

Chapter 2. Literature Review: this chapter reviews the literature on the recent findings on ATM use among people living with HIV who have started taking ART.

Chapter 3. Methodology: this chapter describes the research study design, the method that was used to gather and analyze the data.

Chapter 4. Results: this chapter provides the presentation of the results of the study findings with respect to the first five Objectives.

Chapter 5. Discussion: this chapter discusses the results presented in Chapter 4, specifically with respect to the study Objectives. .

Chapter 6. Conclusion: this chapter answers the research questions and establishes to what extent the Aim has been met. It outlines the study limitations and makes recommendations in line with Objective 6. It outlines the significance of the findings and identifies gaps in knowledge that require further research.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of traditional medicine use among people living with HIV and who take antiretroviral therapy (ART). It explores ART and adherence in general, the reasons for using traditional medicines, factors that could be associated with the decision to consult with a traditional healer, the prevalence of traditional medicines use in patients on ART, the concomitant use of traditional medicine and ART, and the impact of traditional medicine use on ART adherence.

2.2 ART and adherence in general

A number of researchers have described the challenges of adherence to medication and to antiretrovirals (ARVs) in particular, with Chaichati *et al.* (2014), in a study to systematically review interventions to improve adherence to antiretroviral therapy, defining adherence as the extent to which a person uses medication according to medical recommendations, inclusive of timing, dosing, and consistency. In their study, Reda and Biadgilign (2011) defined adherence as taking medications or interventions correctly according to prescription whereas Owen-Smith *et al.* (2007) classified their participants as non-adherent if they reported missing any doses of their antiretroviral medication in the 30 days preceding the baseline assessment. Adherence to antiretroviral therapy (ART) has been a challenge in Africa and globally, as shown by several studies reviewed. However, despite concerns that patients in less-developed settings would be more likely to be non-adherent to ART; a review by Reda *et al.* (2011) indicated that sub-Saharan African patients have the same or higher adherence levels as those in developed countries. A pooled result of a systematic review looking at adherence to ART in India showed a 70% adherence rate (Mhaskar *et al.* 2013). Mathes *et al.* (2014) performed a systematic review to evaluate estimates of ART adherence in Sub-Saharan Africa and North America, with the former being 55% (95% CI: 49%-62%) and the latter 77% (95% CI: 68%-85%). They concluded that favorable levels of adherence in sub-Saharan African settings could be achieved, while adherence in North America remained a concern.

2.2.1 The importance of adherence for clinical outcomes

The World Health Organization (WHO) has explained clearly that “strict adherence to ART is key to sustained HIV suppression, reduced risk of resistance, improved overall health, quality of life and survival, as well as decreased risk of transmission” (WHO, 2003). Adherence to antiretroviral medication to treat HIV is critical, both to maximize efficacy and to minimize the emergence of drug resistance (Peltzer *et al.*, 2010). Adherence is the primary predictor of treatment success with ART, with the inconsistent use of ART being problematic, given its association with both loss of viral suppression and the emergence of drug resistance.

Nachega *et al.* (2012) systematically reviewed ART adherence rates during pregnancy and postpartum in high-, middle- and low-income countries and stated that virologic and clinical success depended on good adherence, with poor adherence enabling the virus to quickly develop therapy-limiting drug resistance.

Even moderate non-adherence to ART has been reported to have significant primary and secondary negative consequences, such as the risk of further compromised cell-mediated immune function leading to opportunistic infections and the development of resistant viral strains (Steele *et al.*, 2001). According to studies on adherence that were reported by Reda and Biadgilign (2011), ART regimens require 70-90% adherence to be effective. However this seems lower than that routinely stated, as the most commonly quoted figure is that 95% adherence is required (Emamzadeh-Fard *et al.*, 2012). A high level of adherence to ART is important for long-term viral suppression to delay progression to AIDS.

2.2.2 Challenges in measuring adherence

The accurate measurement of adherence to antiretroviral therapy is a requirement for HIV care provision, but is also key to research into interventions aimed at maximizing adherence.

Chaiyachati *et al.* (2014), in a study to systematically review global evidence on interventions to improve adherence to antiretroviral therapy from randomized clinical trials, found that more than 20 studies had tested the effectiveness of each of the following interventions: cognitive-behavioural interventions, education, treatment supporters, directly observed therapy and active adherence reminder devices such as mobile telephone text messages. There was strong evidence that all five interventions could significantly increase ART adherence in some settings, but each intervention had also been found not to produce significant effects (Chaiyachati *et al.*, 2014).

Reda and Biadgilign (2011) reviewed articles involving HIV-positive individuals that measured adherence to ART and its predictors in the last decade in Africa, and found different methods for measuring adherence that included direct methods, such as biologic markers and body fluid assays, or indirect methods, such as self-report, interview, pill counts, pharmacy records, computerised medication caps, and viral load monitoring. The studies indicated that self-reports correlated well with both viral load and clinical outcomes, and that, as expected, the use of computerised medication caps was reliable and was less prone to respondent bias.

The definition of what constitutes adherent behaviour has varied though. In a systematic review published in 2011, 12 papers and four abstracts defined adherence as taking 95% or more doses during the measurement period, which ranged from two days to six months (Rachlis *et al.*, 2011). However, five studies defined adherence as being 100%, three studies indicated 90%, while the median adherence proportions in cross-sectional studies were 74.3% (range 25-88%) for published studies alone and 73.6% when three conference abstracts were added. The median adherence levels among the three longitudinal studies included was 58.1%, but this increased to 70% after the three conference abstracts were added. The overall range differed little from the cross-sectional studies reported (37-88%) (Rachlis *et al.*, 2011).

The most commonly used target is that patients should take 95% of doses as instructed, on time and in the correct manner. However, the means to measure adherence range from the simple (recall or pill counts) to the highly technological (computerised medication container caps). If well-conducted, self-report and recall can be used as a reasonable measure of adherence in routine clinical care.

2.2.3 Determinants of treatment adherence – factors associated with poor adherence

Studies have reported many factors as being associated with poor adherence to ART. A systematic review in Asian developing countries (Wasti *et al.*, 2012) reported several factors that hinder adherence to ART, namely:

- patient-related factors (forgetting to take medication on time, being too busy, being away from home, not understanding the treatment, feeling depressed or overwhelmed, lack of motivation);
- socio-cultural factors (stigma and discrimination, fear of being recognized at living with HIV or on ART, fear of disclosure, lack of family support);
- beliefs about medication (did not think pills were needed, pills were a burden, taking pills for a long period); and
- medication side effect, financial difficulties and health-system factors.

Lubega *et al.* (2010) conducted a study in a resource-poor setting in eastern Uganda to explore reasons for drop-out from pre-ARV care, and found that inadequate counseling, competition from traditional or spiritual healers, transportation costs, waiting time, lack of incentives and gender inequality were commonly cited. A study in adult patients of African-American descent, to investigate adherence to HIV treatment and retention in care, found that central nervous system side effects such as dizziness, insomnia, depression and other psychiatric illnesses, particularly in those taking efavirenz, strongly influenced adherence (Snow *et al.*, 2010).

In addition, Snow *et al.* (2010) noted other factors, such as unemployment, lack of effective social support networks, unstable living conditions, incarceration, non-disclosure of HIV status, active alcohol use, patient-level socioeconomic, income and education, as being important. Data from rural Mozambique showed that perceived challenges by community participants and health care workers included the inability to afford food in sufficient quantity or quality, lack of transportation and stigma (Groh *et al.*, 2011). A study of 686 patients at two large ART centres in the Ugandan capital, Kampala, found that cost was the most significant factor causing discontinuation of therapy, followed by negative medication-related side-effects and poor medication supply (Kiguba *et al.*, 2007).

A study in South Africa by Maqudu *et al.* (2010) explored the influence of baseline factors on first month adherence to ART among adult patients. During the first month of ART, 79% of patients were adherent, but this was negatively associated with a higher baseline CD4 count.

In other words, those patients who were more ill were more likely to adhere to treatment. A systematic review that examined adherence to ART in India reported that 50% of studies showed that the cost of medication was an obstacle to treatment adherence, with 25% reporting lack of access to medication, and 12% citing adverse events (Mhaskar *et al.* 2013).

Overall, therefore, there is a consistent thread running through the available evidence, from resource-constrained settings in particular. While high levels of adherence are possible in such settings, a number of factors need to be addressed in order to maximize adherence. These include the avoidance of ART regimens associated with frequent toxicity, careful counseling on those adverse effects that are time-limited in nature (such as the neuropsychiatric effects associated with efavirenz), but also careful attention to such barriers as cost, stigma and poor supply chain management. However, there are studies from African settings that have pointed to the potential for competition between biomedical approaches and those advocated by traditional or spiritual healers who may be consulted by patients on ART.

2.2.4 Measures to improve adherence

Studies reviewed indicate that many measures can be taken to improve adherence to ART. Mathes *et al.* (2014) performed a systematic review to explore estimates of ART adherence impacts in Sub-Saharan Africa and North America and found that short message service (sms) interventions showed a statistically significant effect on adherence (95% CI -0.17 to -0.03), and that modified directly observed therapy (DOT) showed a significant effect on mortality (relative risk 0.75; 95% CI 0.44 to 1.26). A systematic review by Wasti *et al.* (2012) that explored the factors influencing adherence to ART in Asian developing countries, identified facilitators or motivators of adherence to be social support from family and friends, self-efficacy, willingness to live longer, improved overall health, financial assistance, using electronic reminders, obligation to live for family, good relationship with care providers, and worries regarding a fear of drug resistance to improve adherence.

On the basis of the study conducted by Groh *et al.* (2011), which explored barriers to ART adherence in rural Mozambique, it was recommended that several interventions, such as providing food supplementation to patients enrolled in care, integrating traditional healers and religious healers into the biomedical system, and engaging expert patients to mentor those initiating ART, should be used to address those barriers.

As indicated previously, the available data have identified a range of adherence-promoting interventions that have been shown to be effective in resource-poor environments. Of particular relevance to the current study, data from Mozambique, a neighbouring African country, has underlined the need to integrate traditional and religious healers into the biomedical system, in order to address their potential impact on ART adherence.

2.3 ART and the use of traditional, complementary or alternative medicines

In settings where the use of traditional, complementary or alternative medicines is prevalent, it would be expected that patients on ART would also use these medicines. Lubega *et al.* (2010) showed that the reported reasons for drop-out from pre-ARV care in a resource poor-resource setting in eastern Uganda included that the traditional healers provided other forms of pre-ARV services in direct competition to the formal health providers. It appeared that traditional healers were undermining pre-ARV care, as they provided alternative services. Owen-Smith *et al.* (2007) recommended that health care providers and patients should have explicit dialogues about how to effectively integrate traditional practices into biomedical treatment regimens so that the safety and health of HIV-positive patients could be assured.

2.3.1 Reasons for consulting traditional health practitioners

Traditional medicine has been reported to be widely used in African countries, including South Africa. The WHO reported that between 60 and 70% of Africans approach traditional healers as their first line of health care (World Health Organization, 2002). According to the WHO (2008) in some Asian and African countries, it has been claimed that as many as 80% of the population depend on traditional medicine for primary health care. However, these figures have also been questioned and routine data collected annually by the Statistics South Africa (Stats SA) service offer a different picture. For example, the 2015 General Household Survey found that just 0.5% of South Africans reported consulting traditional healers first when household members fall ill or have accidents (Stats SA General Household Survey, 2016). That figure has remained in the range of 0.1 to 0.5% in annual surveys conducted between 2004 and 2015. However, few data are available on the prevalence and patterns of African traditional medicine (ATM) use specifically in patients living with HIV or receiving ART.

A cross-sectional study in Zimbabwe to determine the impact of herbal drug use on adverse drug reactions in patients on ART found that the major reasons for use of African traditional medicines (ATMs) were perceived additional efficacy, improved quality of life, and having control over the disease (Mudzviti *et al.*, 2012). Truter (2007) has listed the reasons that have been given by people for including traditional healing options as follows:

- “know healers quite well;
- visits are not only for health but also for other problems;
- belief that illness arises from supernatural causes and indicates the displeasure of ancestral gods or evil spirits or is the effect of black magic;
- a firmly and irrevocably established health care system throughout the whole continent of Africa;
- forms part of the culture and custom;
- traditional medicine and the various African cultures go together, they cannot be separated;
- lack of satisfaction with treatment;

- lack of trust in the ability of Western medical practitioners to effectively treat psychosocial problems;
- lack of knowledge of Western medical practitioners to treat culture-bound syndromes”.

In a review of reports on the use of ATM amongst those living with HIV, the reasons for their use included: alignment with cultural and/ or religious beliefs, a safe alternative to ARVs, their synergism with ARVs, to alleviate the adverse effects of ARVs, as a general way to promote health and quality of life, and to treat HIV-related fatigue, nausea and pain (Muller and Kanfer, 2011). Simon *et al.* (2010) aimed to identify behavioral aspects of ART preparedness that could be targeted for local interventions to enhance treatment outcomes, and found that 73% of all respondents thought that ARVs worked better than traditional medicine, 56% thought it was not safe to use ART together with traditional medicine, and only 10 % reported that traditional medicine treats HIV/AIDS. Namuddu *et al.* (2011) examined the prevalence and factors associated with ATM use among patients on ART in Uganda, and found that the most stated reasons for traditional medicine use were to reduce fever (67.4%) and treat coughs (65.2%).

In a study that aimed at assessing the use of traditional herbal medicine by AIDS patients in Kabarole District, western Uganda, 137 AIDS patients were selected from outpatient departments of three hospitals (Langlois-Klassen *et al.*, 2007). A questionnaire-based interview found that, overall, 63.5% of AIDS patients had used herbal medicine after HIV diagnosis, while same-day herbal medicine and pharmaceutical drugs were reported by 32.8% of AIDS patients. Patterns of traditional herbal medicine use were quite similar between those on ART and those who received supportive therapy only. The primary conclusion reached was that AIDS outpatients commonly use herbal medicine in that setting. Specifically in South Africa, Babb *et al.* (2007) investigated the use of traditional medicines among HIV-infected individuals attending a workplace clinic where an ART programme had recently been launched. Among 44 interviewees (all male, mean age 42 years), 30 had started ART. Of the respondents 37/44 (84%) reported ever using traditional medicine, and 14/44 (32%) were current users.

Among "ever-users", most obtained traditional medicine from a traditional healer (42%) or herbalist (26%), but 21% obtained these products from their own yards or fields. Frequently-used products included African potato plant (*Hypoxis rooperi*) and *kgala* (*Aloe vera*). Interviewees currently using traditional medicines felt that these remedies made their health "better" (12/14, 86%) or "much better" (2/14, 14%), and none felt that they had side effects. In this small study, 7/14 (50%) current users reported that they were using ATMs specifically for HIV (Babb *et al.*, 2007). Among 23 individuals who had discontinued traditional medicine use, six (26%) reported that this followed advice from health care staff when they started ART. The researchers found that the cost of ATMs varied greatly, depending on the type and source of remedy used.

The common thread in these studies from an African setting is that ATMs are trusted and considered to be safe, but are considered to be complementary to ART, not necessarily as a substitute for ART (Babb *et al.*, 2007, Langlois-Klassen *et al.*, 2007, Namuddu *et al.*, 2011). However, the patterns are not that different in non-African settings. An exploratory study of alternative medicine prevalence and user characteristics in a sample of Dutch gay men revealed that 71% of all respondents reported to have used at least one form of alternative treatment since learning of their HIV serostatus (Knippels and Weiss, 2000). Of this sample, 62.9% reported having used food supplements, 17.1% traditional medicines, 15.7% massage/yoga/meditation/imagery, 21.4% homeopathy and 5.7% acupuncture.

2.3.2 Factors associated with consulting a traditional healer

The subjective reasons for using ATMs may differ from the objective factors associated with their use. As noted above, Knippels and Weiss (2000) conducted an exploratory study of alternative medicine prevalence and user characteristics in a sample of Dutch gay men, and found that symptomatic individuals were more likely to use alternative medicine. Their regression model further suggested that individuals who were more likely to use alternative medicine were those in whom levels of HIV-related pain were low or absent, and those who used active coping strategies in response to HIV-related problems and emotion-focused coping mechanisms.

In an African setting, Taylor *et al.* (2008) examined changes in self-reported health status resulting from accessing either traditional African care (61%) or western medical care (39%) over one month in presumptively HIV-seropositive patients residing in Chipinge, Zimbabwe, a small farming district. They found that patients who received traditional African care versus western medical care sites demonstrated a significantly greater improvement across the majority of quality of life dimensions, such as overall function, disclosure worries, life satisfaction, general health perceptions, physical function, pain, mental health, health distress and provider trust. However, it must be emphasized that these were not confirmed patients with symptomatic HIV disease or on ART. Also from Zimbabwe, Lubinga *et al.* (2012) examined factors associated with the concomitant use of ATM and ART in patients at Mbarara Hospital, and found that the factors identified included time since start of ART, perceived quality of service at clinic, ART regimen, number of attributes of ART informed about, number of ART side effects reported, and self-perceived health status.

In a study among patients on ART in Uganda, single individuals were more likely to use traditional medicine compared to married persons (Namuddu *et al.*, 2011). According to this source, those who were more likely to use traditional medicine were younger than 38 years ($P=0.002$), reported side effects from ART and had been on ART for less than 4 years.

Participants in a qualitative study conducted in Uganda with the aim to investigate the role of HIV testing, counselling and treatment in coping with HIV/AIDS, explained that the early mystic nature of HIV/AIDS caused many to believe it was witchcraft, and that it was this belief that led them to seek traditional and spiritual help rather than medical treatment (Nyanzi-Wakholi *et al.*, 2009). However, although traditional medicines were commended for their nutritional value and traditional healing physically, spiritually and emotionally, traditional medicines were condemned for not having proper dosages, expiry dates and hygienic processes of production. In South Africa, Peltzer *et al.* (2010) conducted a study in three public hospitals in KwaZulu-Natal Province.

They found that, overall, ATM use was associated with younger ages, higher educational level, lower self-reported quality of life, missing ART doses in order to avoid side effects, better self-reported HIV disease, and lower health care information involvement score.

2.3.3 Prevalence and concomitant use of traditional medicines in patients on ART

If the WHO figures are to be accepted, then there is no reason to believe that any less than 60% of African patients on ART would be using ATM, perhaps at the same time. However, if the results of the Stats SA General Household Survey are accepted, then as few as 1% of African patients on ART might be using ATMs at the same time. Data from Uganda showed that 33.7% (95% CI: 33.38-34.02) of patients on ART were using ATM (Namuddu *et al.*, 2011). A study in Kabarole district, western Uganda, found that 38% of HIV-positive patients used ATMs and ARVs at the same time to manage their HIV infection (Langlois-Klassen *et al.*, 2007).

Locally, a cross-sectional survey among young adults of unknown HIV serostatus in Tugela Ferry, KwaZulu-Natal was conducted in order to identify behavioral aspects of ART preparedness that could be targeted by local interventions in order to enhance ART outcomes (Simon *et al.*, 2010). It was found that almost three-quarters (73%) of all respondents thought that ART works better than traditional medicine, while 56% thought that it is not safe to use ART with traditional medicine. Only 10% reported that traditional medicine or spirits can cure or treat HIV/AIDS, and 5% believed that any of the government-advocated folk remedies cured or treated HIV/AIDS. Although only a minority of the respondents in this study reported visiting traditional healers, of these 50% perceived that their healer would recommend traditional medicine only, 24% ART only and 25% both, and 26% thought it would be hard to stop using traditional medicines. However, cross-sectional studies can also be misleading. A study conducted in three public hospitals in Kwazulu-Natal found that ATM use significantly declined from 36.6% prior to ART initiation to 7.9% after being on treatment for six months (Peltzer *et al.*, 2010).

The same group also reported that ATM use declined from the initial 36.6% prior to ART, to 8% after six months, 4.1% after 12 months and 0.6% after 20 months on ART (Peltzer *et al.*, 2011). What is significant here is not only the effect of ART on self-reported ATM use, but the changes over time.

Theoretically, given the paucity of information about potential interactions between poorly characterised ATMs and ARVs, the concomitant use of these medicines should be viewed with caution. In most cases, clinicians and pharmacists would urge patients on ART not to use anything else without consultation. According to Mudzviti *et al.* (2012), the impact of co-administration of traditional herbal medicine with orthodox medicine has not yet been fully evaluated. Researchers in a study that looked at potential pharmacokinetic interactions between ART mentioned that there was evidence from different surveys that some HIV-positive patients also used ARVs and herbal remedies concomitantly, often without the knowledge of their health care providers (Muller and Kanfer, 2011).

2.4 The impact of traditional medicine use on ART adherence

Apart from the potential for drug-drug interactions between ATM and ARVs, there are concerns about the potential for negative effects on ART adherence when patients use ATM at the same time. HIV-positive Ugandans were believed to be twice as likely to quit ART if they also use traditional herbal medicine (Anon, 2007). In this news piece, Dr Ronald Kiguba from Makerere University, stated that the integration of traditional healers into modern medical practice needed to be handled more cautiously: “If these healers can be trained properly in HIV care then they can be a new avenue for clinical care. It's not easy, but the alternative is we continue to lose patients.” Owen-Smith *et al.* (2007) investigated whether traditional medicine use impacted on adherence to prescribed ARV antiretroviral regimens among HIV-positive women, mostly African-American in Alabama and Georgia, with approximately 60% of participants reporting the use of some form of traditional medicine. Women using traditional medicine, relative to non-traditional medicine users, were 1.69 times more likely to report missing ART doses in the last 30 days (95% CI: 1.02-2.80; P=.041), even after adjusting for age, education, race, religion and income.

A study of traditional medicine among patients on ART at Mbarara Hospital in Zimbabwe, examined factors associated with their concomitant use and their impact on ART adherence and found that overall 19.5% (n=65) of participants had poor adherence (Lubinga *et al.*, 2012). Of these, 19.4% (n=30) were concomitantly using traditional medicines but concomitant use of traditional medicine and ART was not associated with poor ART adherence on bivariate analysis (OR 0.99; 95% CI: 0.47-1.53). The only prospectively collected data from South Africa showed that concomitant use of herbal treatment for HIV was associated with reduced ARV adherence among attendees at 3 public sector hospitals in KwaZulu-Natal (Peltzer *et al.*, 2010). The authors recommended that patients' use of traditional medicine should be considered in ARV adherence management.

2.5 Summary

It is clearly evident from the available literature that ATM has been reported to be widely used in Africa settings, as is the case with traditional, complementary and alternative medicines in many other countries. The reasons for the use of traditional medicines vary considerably, but reflect cultural beliefs, religious beliefs, a desire for the alleviation of ART side effects, a desire to achieve additional efficacy in suppressing the virus and managing HIV disease, and a desire for improvement in quality of life. However, several studies have shown that concurrent use of traditional medicine may interfere with adherence to ART.

CHAPTER 3: RESEARCH METHOD

3.1 Introduction

This study examined the extent of use of traditional medicines in patients on antiretroviral therapy (ART), and how this impacted on adherence to ART. This chapter details the type of research, the study location, study population and sample. It details the data collection tools with respect to the study Objectives, the pilot study, how bias was addressed, and the data collection process. It further describes how the data were managed, how the qualitative and quantitative data for the various Objectives was analysed, as well as what ethical issues were addressed, specifically how the participants' confidentiality was maintained and their rights protected.

3.2 Type of research

This study can be broadly categorized as epidemiological research using a descriptive, cross-sectional design with systematic sampling. Descriptive research is used to describe characteristics, such as the size of a problem, the demographic, geographic or distribution of a population being studied. Cross-sectional studies involve the analysis of data collected from a population at one specific point in time and therefore; offer a cost-effective way to gather information from many people in a short period of time.

3.3 Study location

The study was conducted on patients receiving ambulatory ART at the Themba lethu Wellness Centre, Northdale Hospital, a district level referral facility in Pietermaritzburg, the capital city of KwaZulu-Natal province. The facility is located within the uMgungundlovu District Municipality (DC22), and specifically in the Msunduzi Local Municipality (KZN225).

In 2012, the estimated total population of the Msunduzi Local Municipality was 639 575 people (National Department of Health, 2012).

Free ART services were provided to public sector dependent patients who were living with HIV at the hospital's Thembaletu Wellness Centre in accordance with the South African National Strategic Plan for HIV, STIs and TB (2012-2016) (National Department of Health, 2012), and in alignment with the applicable Standard Treatment Guidelines that were in place at that time (National Department of Health, 2010).

3.4 Study population

The population of interest were patients receiving ART from the Thembaletu Wellness Centre in Northdale Hospital, Pietermaritzburg. This health facility served people from all race groups who reside in the suburbs surrounding the hospital, as well as nearby townships and rural areas. Patients were referred from primary health care facilities and were required to visit the clinic monthly once ART has been initiated to receive treatment. The patients seen at the facility were those who were not beneficiaries of a private medical scheme and who could not afford private health care services. In addition, many people of all ages who attended such public sector health facilities relied on social grants as an important source of income (de Paoli *et al.*, 2012), thus indicating a strong reliance on comprehensive public sector services. The clinic was open daily, except Saturday and Sunday, and was serviced by medical officers as well as nurses. In 2015, the public health sector employed 13 656 medical practitioners, 4 986 medical specialists, 68 105 professional nurses and 4 970 pharmacists (Day and Gray, 2015). Only in the case of professional nurses did this represent more than 50% of the health professionals in that category registered by the relevant statutory health council.

3.5 Sample size

Systematic sampling was used to recruit the study population, this entailing that every 3rd participant from the pharmacy queue was selected.

Based on the study done by Langlois-Klassen *et al.* (2007), where it was shown that 63.5% of AIDS patients in a Western Ugandan district had used herbal medicine after HIV diagnosis, the assumption was made that the same proportion of the local sample would be traditional medicine users. A sample size of 49 participants who were prescribed ART was initially considered to be adequate to provide an 80% power to detect a difference between those did and did not used traditional medicines (TMs) of 0.40. However, in order to increase the validity of the study, the sample size was increased to 75 and to account for possible refusals, a total of 80 patients were approached for interviews. Within this study sample on ART, it was assumed that 25% of patients would be using TMs, and 75% would not be using such medicines.

The following inclusion criteria were applied in selecting the participants:

- aged 18-49 years;
- those who had been on ART for at least one year;
- both males and females;
- those who were able and willing to provide informed consent to the study.

The following exclusion criteria were therefore applied:

- outside the range of 18-49 years of age;
- those who had been on ART for less than one year;
- those who were unable or unwilling to provide informed consent, including those patients with mental health problems.

3.6 Data Collection Tools

Data collection tools were used in this study to meet its objectives, the participant questionnaire to collect data and clinic medical records checked to confirm ART adherence. The primary data collection instrument was a semi-structured questionnaire developed by the researcher, based on previous examples used by Langlois-Klassen *et al.* (2007), and Owen-Smith *et al.* (2007) (Appendix A).

This tool was used to address the following objectives; determining the prevalence of African traditional medicines use in patients who are on antiretroviral therapy provided by Northdale Hospital, identifying which African traditional medicines are most commonly used by the patients, describing patients' perceptions about the effectiveness and the safety of the traditional medicines in this setting, investigating factors associated with the use of African traditional medicines by patients on antiretroviral therapy and comparing the level of adherence to ART amongst traditional medicine users and non-users as well as comparing the participants' responses with the data collected from their case files regarding ART adherence.

The questionnaire was translated into the local language (isiZulu) by the researcher, who is a native speaker of the language. The translation was also verified by a second native speaker of isiZulu, who corrected any inconsistencies. The semi-structured questionnaire, with closed and open-ended questions, was used to obtain the following data:

- Socio-demographic such as gender, age, marital status, ethnicity, religion, educational level and number of children.
- Background and beliefs about traditional medicine use such as use of TM, reasons for using TM, type of TM used, beliefs about efficacy of TM especially on treating HIV, beliefs about safety of TM as well as its side effects.
- Factors that could be associated with the decision to consult with a traditional healer included such as educational level, a lack of support, alcohol abuse, lack of knowledge about ART.
- Impact of traditional medicine use on adherence to antiretroviral therapy: such as missing ART doses or stopping ART.

Clinic medical records were checked to determine the ART adherence recorded after patient consultations.

3.6.1 Pilot study

Pilot testing of the questionnaire was completed at the study site with 5 persons living with HIV-infected aged 18-49 years who were not involved in the study.

Information obtained from the pilot study was used to determine the user-friendliness of its contents and the time needed for completion. The information obtained was used to refine the questionnaire, prevent misinterpretation and ensure appropriate data collection.

3.7 Measures taken to reduce bias

Measures taken to reduce potential bias were focused on selection and recall bias, as well as potential confounders.

Selection bias

In the absence of a sampling frame which would have allowed for a random sample of patients from all of those accessing ART at the facility, it was decided to use systematic sampling, with every 3rd participant being selected. The date on which selection commenced was not unusual in any way, and the patients approached for inclusion would therefore be considered to be typical of those accessing ART at the facility.

Recall bias

As people are often not able to recall details accurately, it was important to use the clinic records to obtain data on adherence. Patients were informed that this information would be obtained from their clinic records before they gave consent to participate.

Possible confounders

The potential confounders, factors that could distort the relationship between exposure and outcome, were identified as:

- Factors that could be associated with the decision to consult with a traditional healer, such as educational level, desperation for answers or help and social values.

- Factors that could be associated with non-adherence, such as alcohol abuse, depression, a lack of support, lack of knowledge about ART, cost, negative side-effects, stigma, and poor supply of medication.

Data on these possible confounders were therefore included in the questionnaire design and incorporated into the statistical analysis.

3.8 Data Collection Process

Over a period of two days, 80 patients who were sitting in the queue to see the facility's pharmacy were approached to participate by the researcher. This was done by using systematic sampling and approaching every third person sitting in the waiting queue. Potential participants were given information about the study both verbally and in writing, and were requested to provide written informed consent before being enrolled. They were assured that they would not lose their place in the waiting queue, nor would they be penalized should they decide not to participate. Participants were individually interviewed in a private consultation room adjacent to the ARV pharmacy in the ARV clinic, with each interview taking approximately 10-15 minutes. After the interviews had been completed, the relevant clinic files were requested from the pharmacy to obtain their clinical records.

3.8.1 Data Management

The completed questionnaires were kept in a lockable cabinet in the researcher's residence. The digital data were kept on the researcher's computer, and a backup maintained. Data were provided in electronic format to the statistician. The data will be stored for five years and will be destroyed on instruction of the supervisor.

3.9 Data Analysis

Quantitative data from the questionnaire were captured directly into the Statistical Package for Social Sciences (SPSS 21, Armonk, NY). The data from the closed-ended questions on the questionnaire and the clinical records was first summarized and analyzed using descriptive statistics, namely frequency, percentage, and mean. The test statistic used was the two-sided Fisher's exact test. The significance level of the test was pre-specified at $\alpha = 0.05$. The independent variables were expressed as frequencies and percentages, in a descriptive analysis. Participants' age and number of children were expressed as numerical variables, while gender, marital status, education level, ethnicity and religion were expressed as categorical variables. The strength of association between reported traditional medicine use and non-adherence was assessed. The significance of such associations was assessed using Pearson's chi-square test. Thereafter, binary logistic regression analysis was used to control for the effects of potential confounding factors and multivariate logistic regression; using the backward Wald elimination

3.10 Ethical Considerations and Confidentiality

The following ethical considerations were observed:

- The research protocol was approved by the Post-Graduate Education Committee (Appendix B) and the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BE193/010; Appendix C).
- Permission to conduct this study at Northdale Hospital was also obtained from the hospital manager (Appendix D).
- All participants were provided with the information verbally as well as in writing, and each being required to sign the consent form before entering the study (Appendix E).
- Participation in the study was strictly on a voluntarily basis. No participants were identified by name during the survey or in any records created for the study. All information obtained was kept confidential.
- This study was conducted in compliance with the principles included in the Declaration of Helsinki.

3.11 Summary

In order to achieve the study objectives, data were collected from the study participants using a semi-structured questionnaire, while the clinic files were requested from the pharmacy to obtain the clinical records to obtain data on ART adherence. This enabled a comparison of information obtained from medical records with the data collected using the questionnaire.

CHAPTER 4: RESULTS

4.1 Introduction

This study was undertaken to establish the extent of use of traditional medicines in patients who are on antiretroviral therapy, as well as how this impacts on their adherence to medication. The results are presented with respect to the first five study objectives, the data being obtained from a questionnaire survey of patients attending Northdale Hospital in Pietermaritzburg.

The specific objectives were:

- To describe the prevalence of African traditional medicines use in patients who are on antiretroviral therapy provided by Northdale Hospital.
- To identify which African traditional medicines are most commonly used by the patients.
- To describe the patients perceptions about the effectiveness and safety of traditional medicines in this setting.
- To investigate factors associated with the use of African traditional medicines by patients on antiretroviral therapy.
- To compare the level of adherence to ART amongst users and non-users of African traditional medicines, as recorded by the Northdale ARV pharmacy.

4.2. Socio-demographic characteristics

As shown in Table 4.1, the majority of respondents were females (56/75; 75%), with a mean age of 33.9 years (SD: 7.1 years; range 20 to 49 years). The majority of the study participants were single (44/75; 58.7%), with 21.3% (16/75) being married, 9.3% (7/75) cohabiting (that is, living together but not formally married), 8% (6/75) widowed and 2.7% (2/75; 2.7%) being divorced. Most participants were Black Africans (71/75; 94.7%), with only a few self-identifying as Coloured (2/75; 2.7%) or Indian (1/75; 1.3%), and one who chose to self-identify as “other” (1/75; 1.3%).

The distribution of self-reported religious affiliation of the respondents showed that the overwhelming majority considered themselves to be Christians (63/75; 84%), with only a few reporting to follow the Shembe religion (7/75; 9.3%) or Hindu (1/75; 1.3%) faiths. Four respondents chose to report their religious affiliation as “other” (4/75; 5.3%). The highest attained educational level reported was, primary education (33/75; 44%), followed by secondary level education (28/75; 37.3 %). Only a few reported having completed tertiary level education (9/75; 12%), and five of the 75 respondents (6.7%) reported having no education at all. Only 14/75 respondents (18.7%) reported having no children, with the majority (53.2%) having either one or two children, and five women reporting having six and more children.

Table 4.1: Demographic details (n=75)

Variable	Characteristic	No.	%
Gender	Male	21	25.0
	Female	56	75.0
Age	20 – 24	6	8.0
	25 – 29	20	26.6
	30 – 34	14	18.6
	35 – 39	17	22.6
	40 – 44	13	17.3
	45 – 49	5	6.6
Marital status	Single	44	58.6
	Married	16	21.3
	Widowed	6	8.0
	Divorced	2	2.6
	Cohabiting	7	9.3
Ethnicity/ race	Black African	71	94.6
	Coloured	2	2.6
	Indian	1	1.3
	White	0	0
	18 Other	1	1.3
Religion	Christian	63	84
	Hindu	1	1.3
	Shembe	7	9.3
	Muslim	0	0
	Other	1	1.3
Highest attained education level	Primary	33	44.0
	Secondary	28	37.3
	Tertiary	9	12.0
	No education	5	6.6
Number of children	0	14	18.7
	1	25	33.3
	2	15	20.0
	3	9	12.0
	4	4	5.3
	5	3	4.0
	6	4	5.3
	9	1	1.3

4.3 Prevalence of African traditional medicines use in patients who are on ART provided by Northdale Hospital

Of the 75 study participants who were asked if they had used traditional medicines in the 28 days preceding the survey, only 9.3% (7/75) reported having done so as shown in Table 4.2. However, almost half of those taking traditional medicine indicated that they had missed doses of ART.

Table 4.2: Traditional medicine use by participants

	Yes	No
	No. (%)	No. (%)
Use of traditional medicine in the past 28 days	7 (9.3%)	68 (90.7%)
Any ART missed doses due to traditional medicine use	3 (4.0%)	72 (96.0%)

4.4 African traditional medicines most commonly used by the patients

The types of African traditional medicine reported as having been used previously by the study participants were *Intelezi* (2/75; 2.7%), *Imbiza* (1/75; 1.3%), *Imbiza* herbal tonic (1/75; 1.3%), vomit inducer (1/75; 1.3%), and *umuthi omhlophe* (1/75; 1.3%). In addition, one participant (1.3%) reported the use of an un-named traditional medicine (Table 4.3).

Table 4.3: Type of Traditional Medicine used by participants

Type of Traditional medicine used	No.	Percent
Intelezi	2	2.7
Imbiza	1	1.3
Imbiza herbal tonic	1	1.3
Vomit inducer	1	1.3
Umuthi omhlophe (White medicine)	1	1.3
Name not known	1	1.3

Although the majority of participants (68/75; 90.7%) did not report having used traditional medicines, those who did (7/75; 9.3%) provided a number of reasons for their use, including both health and cultural factors (Table 4.4).

Table 4.4: Reasons for using traditional medicine by participants

Reasons for using traditional medicines	No.	Percent
<i>Indiki</i> (Temporal spirit possession of godfather)	1	1.3
General cleansing purposes	1	1.3
Cleansing purpose after death of a family member	1	1.3
Cleansing the body	1	1.3
Cultural function	1	1.3
Protection against bewitching	1	1.3
To win a court case	1	1.3
Total	7	9.3

4.5 Patients' perceptions about the effectiveness and safety of traditional medicines

Almost half of the participants (36/75; 48%) strongly disagreed that traditional medicines were effective in controlling HIV infection, as indicated in Figure 4.1.

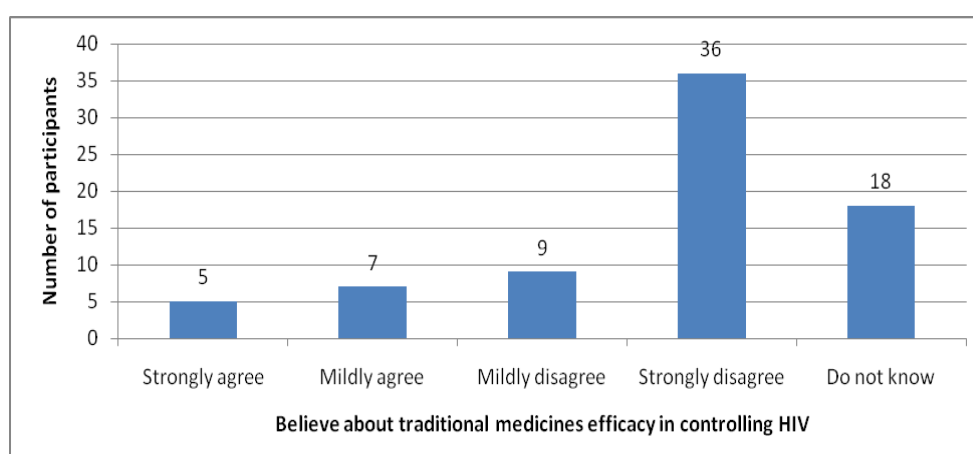


Figure 4.1: Participants' belief in efficacy of traditional medicine to control HIV infection (n=75)

Table 4.5 summarises the participants' beliefs about the safety of traditional medicines. The majority of respondents (56/75; 74.6%) did not believe that traditional medicines were safe to use, while 25.3% (19/75) felt that they were safe. Almost half (37/75; 49%) of the participants believed that traditional medicines were associated with adverse (side) effects.

Table 4.5: Participants' belief about safety of traditional medicines (n=75)

	Yes	No
	No. (%)	No. (%)
Do you believe that it is safe to use traditional medicines?	19 (25.3%)	56 (74.7%)
Do you believe that traditional medicine have side effects	37 (49.3%)	38 (50.7%)

4.6 Factors associated with the use of African traditional medicines by patients on ART

All of the participants (7/75) who admitted to having previously used traditional medicines were Black African males. Most of these respondents were single (57.1%; n=4/7), as shown in Table 4.6.

Table 4.6: Marital status of participants who used traditional medicines (n=7)

Marital Status	No.	%
Single	4	57.1
Married	1	14.3
Widowed	1	14.3
Cohabit	1	14.3
Divorced	0	0
Total	7	100

The majority of participants who took traditional medicines followed the Christian religion (71.4%; n=5/7), while two (28.6%) were Shembe followers (Table 4.7).

Table 4.7: Religion of participants that used traditional medicines (n=7)

Religion	No.	%
Christian	5	71.4
Shembe	2	28.6
Hindu	0	0
Muslim	0	0
Other	0	0
Total	7	100

In terms of educational level, three of the participants who consumed traditional medicines had secondary level of education (42.9%, n=3/7), followed by two who had primary (28.6%, n=2/7), and one each who had tertiary (14.3%; n=1/7) and no education (14.3%; n=1/7). The distribution is depicted in Figure 4.2.

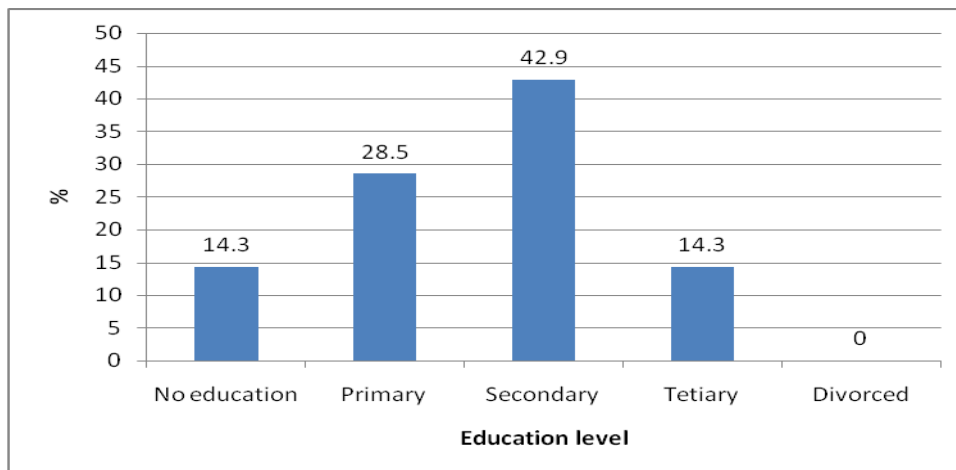


Figure 4.2: Educational level for participants who reported using traditional medicine and ART concomitantly

4.7 Level of adherence to ART amongst users and non-users of African traditional medicines, as recorded by the Northdale ARV pharmacy

The adherence measure for the whole sample showed that 20% (n=15) of participants had missed some antiretroviral doses in the past 28 days (Objective 5).

Table 4.8 summarizes the impact of ATM use on adherence and shows that out of the seven individuals that had used traditional medicines, three (42.9%) had missed ART doses (i.e. $3/7 \times 100 = 42.9\%$) and that out of the 68 participants who had not used traditional medicines, 12 had missed their ART doses (i.e. $12/68 \times 100 = 17.7\%$), therefore 17.7% is the proportion of participants that were not using traditional medicines but skipped some of their ART medicines doses. The null hypothesis was that the use of traditional medicines has a negative effect on ART adherence. Test for proportion was used to calculate the difference between the proportion of ATM users and non-ATM users who had missed ART. On the basis of Chi-square test, $p=0.545$ and Chi-square= 0.366 therefore indicates that the findings were not statistically significant.

Table 4.8: Antiretroviral doses missed by users and non-users of traditional medicines

Missed ART doses	ATM users		Non-ATM users	
	No.	%	No.	%
Yes	3	42.9	12	17.7
No	4	57.1	56	82.3
TOTAL	7	100	68	100

For the purposes of this study, non-adherence was defined as missing three or more doses of antiretroviral treatment in a period of one month. Table 4.9 shows that, of the seven individuals who reported having used African traditional medicines, only one (1/7; 14.3%) missed more than three doses of ART in the month preceding the study. Of the remaining 68 participants who reported not having used African traditional medicines, five (5/68; 7.4%) of the 12 who had missed their ART had missed more than three ART doses during the same period. The difference in non-adherence between users and non-users of African traditional medicines was not statistically significant, whether tested by means of a two-sided Fisher's exact test ($p=0.522$) or a Chi-squared test ($p= 0.41$).

Table 4.9: Adherence status of traditional medicine users and non-users

Adherence status	ATM users		Non-ATM users	
	No.	%	No.	%
Adherent participants	6	85.7	63	92.6
Non-adherent participants	1	14.3	5	7.4
TOTAL	7	100	68	100

However, based on multivariate logistic regression; using the backward Wald (elimination) method, male sex and the use of traditional medicines were identified as variables that significantly predicted the likelihood of an individual missing at least 3 doses of ART (Table 4.10).

Table 4.10: Multivariate Logistic Regression Model

Variable	P value
Sex (male)	0.005*
Age	0.205
Marital status	0.488
Ethnicity	0.689
Religion	0.485
Traditional medicine use in the past 28 days	<0.0001*
Overall statistics	<0.0001

*statistically significant

4.8 Summary

Based on the questionnaires administered to 75 patients receiving ART at Northdale Hospital in Pietermaritzburg, and self-reported use of African traditional medicines, as well as assessment of adherence to ART, male sex and the use of African traditional medicines were shown to be associated with poor adherence (missing at least 3 doses of ART in a month).

CHAPTER 5: DISCUSSION

5.1. Introduction

This Chapter provides a discussion of the findings presented in the preceding chapter and places them in the context of the available literature on traditional medicine use by patients who antiretroviral therapy and on the effect of such concomitant use on adherence to ART.

5.2. The extent of use of ATM by patients on ART

The available literature, as reviewed in Chapter 2, shows that ATM has been reported to be widely used in Africa, as is the case with traditional, complementary and alternative medicines in many other countries. The reasons for the use of traditional medicines vary considerably, including by those who are also receiving ART. The available literature points to a combination of factors such as, cultural and religious beliefs, a desire to alleviate ART side effects, to achieve additional efficacy in suppressing the virus and managing HIV disease, to improve their quality of life. However, there is also evidence that points to a potentially far lower prevalence of use of ATM by South Africans. Each year, Statistics South Africa conducts the General Household Survey among a nationally-representative sample of the population (Statistics South Africa, 2015). The 2015 survey was conducted among residents of private households in all nine provinces of South Africa as well as workers' hostels. It does not include those living in other collective living quarters, such as students' hostels, old-age homes, hospitals, prisons and military barracks. One of the standard question posed is about the type of health care facility consulted first by households when a household member fall ill or has an accident. In 2015, only 0.5% of respondents indicated that they would first seek help from a traditional healer (Statistics South Africa, 2015; 23). That figure has remained remarkably stable since 2004, varying from a low of 0.1% in 2011 and 2013 to a high of 0.6% in 2005 (Statistics South Africa, 2015). The key element maybe the way the question is posed.

While many South Africans may not “first” seek help from a traditional healer, they may still use ATM in addition to Western medicines at some stage in the process of care, such as during chronic ART.

The prevalence of ATM use among patients on ART at Northdale Hospital in Pietermaritzburg was found to be lower than was initially expected (7/75 participants; 9.3%). However, this finding may be an underestimate of the true prevalence, either due to the small sample size and/or social desirability bias. The data were based on self-reports elicited by a pharmacist in a hospital setting where traditional medicine use alongside ART is usually discouraged. Previous surveys showed a higher prevalence of various types of TM by patients receiving ART. For example, Namudduet *et al.* (2011) showed that one in every three patients (33.7%) on ART in Uganda used traditional medicines at the same time. Hughes *et al.* (2012) showed that 16% of participants on ART reported TM use. Lubinga *et al.* (2012) reported that 46.4% of participants in their study were using TM in addition to ART. Mudzviti *et al.* (2012) found that 98.2% of participants in a site in Zimbabwe were using at least one herbal medicine together with ART. The use of traditional medicines was also evident in settings other than those in Africa. Knippels and Weiss (2000) found that 71% of HIV-positive Dutch gay men used at least one alternative therapy since first receiving notification of HIV serostatus, alone or in combination with other medicines.

As identified in a systematic review by Rachlis *et al.* (2011), social factors such as marital status and having children can impact on ART adherence. Wasti *et al.* (2012) published a systematic review of factors influencing adherence to ART, but specifically in Asian developing countries. They identified the factors impeding adherence to ART as socio-cultural, financial, health system and drug-related factors. Age, sex, marital status, religion and educational level were therefore selected as potential predictors of traditional medicine use in this study. All of the participants who admitted to having used traditional medicines were Black African males (7/7; 100%). The majority (4/7; 57.1%) were single, and 5/7 (71.4%) followed a Christian religion. Just less than half (3/7; 42.9%) had a secondary level of education.

The mean age of the participants in the current study (33.9 years) was comparable to that of the participants in the study conducted by Langlois-Klassen *et al.* (2007; 36 years), Mudzviti *et al.* (2012; 40.8 years), Hughes *et al.* (2012; 37 years, Malangu (2007; 36.7), and Namuddu *et al.* (2011; 39 years). Hughes *et al.* (2012) showed that traditional medicine use was more common in an older age group (38-62 years; 17.4%) than in a younger age group (19-37 years; 13.7%); $n=7$). However, in the present study, no significant relationship was found between age and use of traditional medicine ($p=0.205$).

The majority of participants in the present study were females (54/75; 72%), which was also consistent with previous surveys conducted in African settings. Malangu (2007) included 68.9% females, Langlois- Klassen *et al.* (2007) reported on 70.1% females, Mudzviti *et al.* (2012) showed 64.7% females, and Hughes *et al.* (2012) 70.1% females. This is important as all participants in the present study who self-reported having used traditional medicines in the preceding 28 days were males. By contrast, Langlois-Klassen *et al.* (2007) showed that concurrent use of traditional herbal medicine and pharmaceutical medicines was statistically significantly more common among female respondents (34.7%) compared to male respondents (17.1%; $p= 0.038$). This finding was also reported by Hughes *et al.* (2012), although the number of traditional medicine users was small (11 female and 4 male). Namuddu *et al.* (2011) also found that TM use was higher among women (36.4%) compared to men (27.3%). However, given the small number of participants in the current study who self-reported using ATM ($n=7$), this finding should not be over-emphasised. As in many African settings, the majority of patients on ART in South African public sector facilities are women, reflecting not only the effects of differential health-seeking behaviour and stigma, but also the impact of antenatal care and testing. Given the setting for the present, study, the inclusion of a majority of black Africans participants was not surprising. The role of ethnicity was not explored in other studies conducted in an African setting, though Langlois-Klassen *et al.* (2012) did report on tribal identity.

In the present study, the majority of participants (58.7%) were single, which was comparable to the figures reported by Malangu (2007; 77.8%). Hughes *et al.* (2012) found that the majority of participants (73.2%) in their study were never married.

However, Langlois-Klassen *et al.* (2007) reported that the largest proportion of study participants (42.3%) was married. Namuddu *et al.* (2011) showed that single individuals were more likely to use TM compared to married individuals ($p=0.006$), and those older than 39 years were less likely to use TM than those who were less than 38 years ($p=0.002$).

Hughes *et al.* (2012) reported that participants were more likely to use TM if they were from a rural province, female, older, unmarried, employed and had limited education. In the present study, marital status was not a statistically significant predictors of traditional medicine use and non-adherence to ART ($p=0.488$).

Most participants in the present study (33/75; 44%) had achieved no more than a primary level of education. Hughes *et al.* (2012) showed a similar picture, where the majority (73.2%) had less than high school education. Langlois-Klassen *et al.* (2007) also drew from a similar sample, where the majority (57.7%) had no more than a primary school education, as did Namuddu *et al.* (2011; 50.9%). The participants in the study conducted by Malangu (2007) were more highly educated, with 73.9% having reached high school education. Hughes *et al.* (2012) showed that traditional medicines were used to a greater extent by those who had no schooling (31.3%) compared to those who had some education (12.4%). Although the numbers are probably too small to draw any conclusions, in the present study traditional medicines were used by participants who had secondary level of education (3/7; 42.9%), primary education (2/7; 28.6%), tertiary (14.3%; $n=1/7$) and no education at all (1/7; 14.3%).

In the present study, the majority of participants (81.3%) reporting having had children. In the study conducted by Hughes *et al.* (2012), 83.5% of participants reported having children, and traditional medicine use was more common amongst these participants (17.1%) than among those who reporting having no children (6.3%). However, caution is warranted as the numbers of participants was small (14 versus 1 participant, respectively).

5.3 African traditional medicines used and reasons for use

Several studies in the literature have reported a variety of traditional medicines used by patients who are on ART. In the present study the majority (68/75; 90.7%) denied any use of traditional medicine. Drawing too many conclusions from the small number of study participants (7/75; 9.3%) who self-reported using traditional medicine while on ART is therefore not recommended.

The compositions of most traditional medicine mixtures are not specified to users by traditional health practitioners or sellers of such products. Some participants therefore did not know the names of traditional medicines they were using, and in some cases, only the indication for use could be reported. This made it difficult to compare the types of ATMs reported to be used in the present study and to compare these with the ATMs reported in other surveys. The traditional medicine used by study participants were described as *Intelezi* (2/75; 2.7%), *Imbiza* (1/75; 1.3%), *Imbiza* herbal tonic (1/75; 1.3%), vomit inducer (1/75; 1.3%), *umuthiomhlophe* (white medicine) (1/75; 1.3%). In addition, one user (1/75; 1.3%) did not know the names of the traditional medicines he had used. Babb *et al.* (2007) reported that, in their study, the frequently-used products were African potato plant (*Hypoxisrooperi*) and *kgala* (*Aloe vera*). In stark contrast, though, Hughes *et al.* (2012) reported that the most popular ATM was a herbal mixture described as *ubhejane*. Malangu (2007) reported the use of African potato (*Hypoxishemerocallidea*) and coconut (*Cocosnucifera*), but also of unspecified traditional mixtures. Namudduet *al.* (2011) described the use of locally mixed stems, wood barks, leaves, food supplements and individual morning urine. Mudzviti *et al.* (2012), who conducted their study in a Zimbabwean setting, described the use of *Allium sativum* (72.7%), *Bidens pilosa* (66.0%), *Eucalyptus globulus* (52.3%), *Moringa oleifera* (44.1%) *Lippia javanica* (36.3%) and *Peltoforum africanum* (34.3%).

The reasons for use can be an illumination of the listed ingredients. With the usual caveat that the number of reported users was low, the present study participants listed general cleansing purposes (1/75; 1.3%), cleansing purposes (1/75; 1.3%), cleansing after death of a family member (1/75; 1.3%), cleansing of the body (1/75; 1.3%, cultural functions including cleansing purposes (1/75; 1.3%), protection against bewitching (1/75; 1.3%) and use in order to win a court case (1/75; 1.3%).

It is clear that these reasons can be more generally grouped as relating to “cleansing” (perhaps for cultural reasons) and for uses related to traditional beliefs (such as in the role of “bewitching” as a cause of disease or bad luck). Truter (2007) reported the reasons for traditional medicine use as to be: “know healers quite well”, “visits not only for health problems but also for other problems”, and “belief that illness arises from supernatural causes”. Participants in a survey by Hughes *et al.* (2012) indicated that they had used traditional medicine to gain strength, increase their appetite, and relieve symptoms of numbness, ulcers and bad dreams. Similarly, Langlois-Klassen *et al.* (2007) reported that the predominant reason for traditional herbal medicine use by patients receiving ART was that they wanted relief from the symptoms they experienced. The most common reasons given for their use in the study performed by Langlois-Klassen *et al.* (2007) were, in descending order of frequency: availability of traditional medicine (32.6%), traditional medicine effectiveness (14.6%), proximity of herbs to the patient (16.3%), familiarity with traditional medicine (10.9%), and affordability (9.3%). Namuddu *et al.* (2011) also recorded reasons related to the relief of symptoms, such as to reduce constant fever (67.4%) and treat cough (65.2%).

Almost half of the participants in the present study (36/75; 48%) did not agree with the statement that traditional medicines were effective in controlling HIV infection. However all the participants who self-reported having used traditional medicine indicated that had helped them in some way. This finding is broadly in concert with those reported elsewhere. Babb *et al.* (2007) reported that 86% of participants in their study who were using traditional medicines felt that they made their health ‘better’ or ‘much better’.

In a study done by Langlois-Klassen *et al.* (2007), they found that 14.6% of participants believed in traditional medicines' effectiveness. Simon *et al.* (2010) looked at the preparation for ART rollout in rural South Africa and found that 73% of respondents believed that ART works better than TM, and that 56% thought it was not safe to use ART concomitantly with TM. Namuddu *et al.* (2011) reported that 96.3% of patients on ART who reported using TM perceived better health and that those who reported side effects from ART were two times more likely to use TM compared to those who did not. -In the present study, few of the participants (20/75; 26.7%) believed that it was safe to use traditional medicines. Accordingly, almost half (37/75; 49%) believed that traditional medicines were associated with adverse (side) effects. This may well be the consequence of conditioning by the hospital health workers, or reflect potential social desirability bias. For example, Babb *et al.* (2007) reported that users tolerated traditional medicines well and that none felt that they had side effects.

5.4 Impact of traditional medicine use on adherence to antiretroviral therapy

The aim of the present study was to examine whether use of ATM was associated with decreased adherence to ART. However, as very few of the study participants (7/75; 9.3%) admitted to having used ATM concurrently with ART, drawing any conclusions from these data is difficult. The results indicated that, of the seven individuals who reported using traditional medicines, three (42.9%) also reported having missed ART doses. Nonetheless, the bivariate analysis indicated that the variables that were significantly associated with non-adherence to ART were traditional medicine use and male sex ($p=0.005$) and the use of traditional medicines ($p<0.0001$).

Owen-Smith *et al.* (2007) investigated the relationship between complementary/alternative medicine (CAM) use and ART adherence and found that women using CAM, relative to non-CAM users were 1.69 (95% CI: 1.01-2.80; $p=0.41$) times more likely to report missing ART doses in the preceding 30 days, even after adjusting for age, education, race, religion and income.

This finding was previously reported in South Africa, where Peltzer *et al.* (2010) found that, based on multivariate analysis regression analyses, ARV non-adherence (in relation to dose, schedule and food) was associated with the use of herbal treatment, but not with taking micronutrients or using non-prescription medicines. Namuddu *et al.* (2011) reported that patients whose adherence level was below 95% were more likely to use traditional medicine. However, the relationship between traditional medicines use and reduced ART adherence has not always been detected. Lubinga *et al.* (2012) found that widespread concomitant herbal medicines had no association with poor ART adherence in a Ugandan setting (OR 0.85; 95% CI; 0.47-1.53).

The relationship has also not held true in non-African settings. Knippels and Weiss (2000) investigated the use of alternative medicine in a sample of Dutch HIV-positive gay men, and reported that users had better adherence to ART than non-users. However, such a finding may be the result of a confounding variable, such as greater concern about health and well-being among users of alternative medicines than among non-users. Those with greater concern about health and well-being may be more adherent to prescribed treatments, including ART.

5.5 Summary

Although the present study did confirm the relationship between concomitant use of ATM and poor adherence to ART, the data did present a number of important limitations. Few conclusive findings can be extracted with any confidence from such a small sample of concurrent users. Nonetheless, the potential interaction between ATM use and ART, either at the level of potential pharmacological or pharmacokinetic drug-drug interactions or at the level of effects on adherence and health-seeking behaviour, cannot be ignored. Recommendations for practice are accordingly offered in the next chapter. Although the extent of concurrent use may appear low, this may be an under-estimate of the true prevalence of ATM use by patients who are receiving ART. Social desirability bias, or the impact of instrument design may, as is seen in the annual General Household Survey, result in consistent under-estimation of the exposure of interest.

The reasons for ATM use are often as much cultural and health-related, and are therefore unlikely to be avoided by simple admonitions not to co-administer such treatments. The evidence gathered in other settings, particularly in African countries, cannot be ignored.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

The primary motivation for conducting this study was that there is limited information about the use of traditional medicine among patients receiving ART in South Africa. There were reasons to believe that this was a common practice, but little was known about how and why ATM was used, and how its use might affect adherence to ART, a key determinant of patient outcomes. A particular concern was that the use of traditional medicine might be associated with increased non-adherence to ART. This Chapter discusses the significance as well as the conclusion and recommendations based on the findings of the study.

6.2 Significance of the study

Although only 9.3% of participants admitted to have used traditional medicines in this the survey, this indicates that there is still minority of patients that use traditional medicines and ART together. It is crucial that continued patient counseling regarding medication such as dangers of drug-drug interactions are discussed and reinforcement of adherence to ART at every clinic visit is emphasised. Another interesting finding was that participants did not seem have enough knowledge about the types of the traditional medicines they were using. This indicates the importance of strengthening the relationship between traditional health practitioners and the formal health sector. This can be achieved, for example, by including traditional health practitioners on hospital boards or clinic committees, and by creating opportunities for contact between such practitioners and health professionals such as medical practitioners, nurses and pharmacists at continuing professional development events.

6.3 Study limitations

Despite previous studies having shown far higher prevalence of concomitant ATM use with ART, the present study identified only a small number of participants (all African males) who reported missing ARV doses and who also self-reported traditional medicine use. A major limitation of this study was that it was cross-sectional, and therefore captured only a “moment in time”. Ideally adherence patterns to any treatment should be tracked over a sustained period of time. In addition, social desirability bias could not be eliminated entirely, even though the researcher was non-judgmental and able to engage participants as an African. Nonetheless, the effect of being asked about a practice that is actively discouraged in the health care setting cannot be ignored. Recall bias can also not be excluded. Due to the small sample size, the results may not be generalizable to all patients who attend ART clinics in the public sector in South Africa, let alone in Africa or in other settings.

6.4 Recommendations

Accordingly, the following recommendations are offered:

- Healthcare providers should routinely screen patients for traditional medicine use when initiating antiretroviral therapy and also during follow-up and monitoring, keeping in mind that these patients may not fully disclose all medicines or therapies that they are using. It is imperative that a non-judgmental approach is used, implicitly giving patients the space to be open and honest about their health-seeking behaviour, and about the full range of practitioners and practices they may have consulted and used or may plan to consult or use. This should, hopefully counter the potential impact of social desirability bias in the responses provided, and thus the completeness of the data on which clinical decisions can be made. Pharmacists can play a key role being the interface between ART prescriptions and patient access, their knowledge about medicines formulations can assist patients in understanding the complications associated with the use of other remedies, such as traditional medicines.

- A strengthened relationship between traditional health practitioners and the formal health sector must be fostered. In this regard, the full implementation of the Traditional Health Practitioners Act (Act 35 of 2004) must receive attention, so as to effectively regulate both training and practice.
- Further studies, utilising larger and more diverse samples and longitudinal designs are required to give a more accurate estimate of the true prevalence of traditional medicine use among patients already on antiretroviral therapy, as well as the impact of such use of adherence and, ultimately, on patient outcomes.

6.5 Conclusion

In the present study, only 9.3% of participants admitted to having used traditional medicines in the 28 days preceding the survey. Nonetheless, participants were more likely to be non-adherent to ART if they were male and self-reported using traditional medicine. This finding, which broadly supports those generated elsewhere in African settings, has direct relevance for the counseling provided to patients on ART.

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Appendix A

Questionnaire

Traditional medicine use questionnaire

1. Personal Details

a. Gender

Male	
Female	

b. Age:years

c. Marital status

Single	
Married	
Widowed	
Divorced	
Living with a partner	

d. Ethnicity

African	
White	
Coloured	
Indian	
Other	

e. Religion

Christian	
Muslim	
Hindu	
Shembe	
Other	

f. Educational level

Primary	
Secondary	
Tertiary	
None	

g. Number of children:_____

2. Use of traditional medicines

a. Do you believe that ART has helped you in any way? please explain._____

b. In your own terms, how would you define ART?

c. For how long have you been on ART?

d. 'ART is effective in controlling HIV infection'

Strongly agree	
Mildly agree	
Mildly disagree	
Strongly disagree	
Do not know	

e. Do you it is safe to use ART? Please explain.

f. Did you experience any side effects?

Yes	
No	

g. If yes, how did you handle them?

h. What brought you to the clinic for ART?

i. Do you have enough support from your partner, family or friends regarding HIV and ART?

Yes	
No	

j. In the past 28 days did you miss any antiretroviral medicine doses due to traditional medicine use?

Yes	
No	

k. If yes, how many doses of ARVs did you miss?

Less than 3	
More than 3	

l. Have you ever missed ART dose due to poor supply from your hospital?

Yes	
No	

m. Who/ what introduced you to traditional medicine use in your life?

--

n. In the past 28 days, did you use any traditional medicine?

Yes	
No	

o. If yes, did you continue to take your ARVs whilst using traditional medicine?

Yes	
No	

Explain:_____

p. What was the reason for using traditional medicine use?

q. For how long did you use traditional medicine? _____

r. What type of traditional medicine did you use?

--

s. Do you believe that it has helped you in anyway?

Yes	
No	

t. Do you believe that traditional medicine is effective in controlling HIV infection?

Strongly agree	
Mildly agree	
Mildly disagree	
Strongly disagree	
Do not know	

u. Is it safe to use traditional medicine?

Yes	
No	

v. Does traditional Medicine have any side effects?

Yes	
No	

w. Would you use traditional medicine in future?

Yes	
No	

x. How many units of alcohol do you consume per week?

--

Appendix B

Postgraduate Education & Research Committee Approval

01 November 2011

Mr A Gray
Department of Therapeutics & Med. Mngt.
NRMSM

Dear Mr Gray

PROTOCOL: Traditional medicine use in HIV positive patients at Thembaletu Wellness Centre in Northdale Hospital: Prevalence, factors influencing it and its impact adherence to antiretroviral therapy (ART). M-PH, ZYP Mazibuko, SN 9509250


The Postgraduate Education & Research Committee ratified the approval of the abovementioned study on 01 November 2011.

Please note:

- The Postgraduate Education Committee must review any changes made to this study.
- The study may not begin without the approval of the Biomedical Research Ethics Committee.

May I take this opportunity to wish the student every success with the study.

Yours sincerely



Professor SJ Botha
Chair: Postgraduate Education & Research Committee



CC. ZYP Mazibuko

Biomedical Research Ethics Committee
Westville Campus






Postgraduate Education Administration
Medical School Campus

Postal Address: Private Bag 7, Congella, 4013, South Africa

Telephone: +27 (0) 31 260 4495 Facsimile: +27 (0) 31 260 4723 Email: mbokazi@ukzn.ac.za Website: www.ukzn.ac.za

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Appendix C

Biomedical Research Ethics Committee Approval



UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website: <http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx>

17 November 2011

Dr. ZYP Mazibuko
PO Box 266
Bergville
3350
e-mail: zmazibuko@phidisa.org

Dear Dr Mazibuko

PROTOCOL: Traditional medicine use in HIV positive patients at Thembaletu Wellness Centre in Northdale Hospital: Prevalence, factors influencing it and its impact on adherence to antiretroviral therapy (ART). REF: BE193/010

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 23 September 2010.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 09 November 2011 to queries raised on 08 November 2011 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 17 November 2011.

This approval is valid for one year from **17 November 2011**. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/ResearchEthics11415.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its next meeting taking place on **13 December 2011**.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely



Professor D.R. Wassenaar
Chair: Biomedical Research Ethics Committee

Appendix D

Hospital Manager Approval

APPENDIX 9

PERMISSION TO CONDUCT A RESEARCH STUDY/TRIAL

This must be completed and submitted to the Medical Superintendent/s / Hospital Manager for signature.

For King Edward VIII Hospital (KEH) and Inkosi Albert Luthuli Central Hospital (IALCH) studies please submit together with the following:

- i) Two copies of the final, approved protocol
- ii) Letter giving provisional ethical approval
- iii) Details of other research presently being performed by yourself (individually or as a collaborator)
- iv) Details of any financial or human resource implications to King Edward VIII Hospital
- v) If a clinical trial, please produce proof of payment or intention thereof to KEH

Once the document has been signed it should be returned to this office so that full ethical approval can be granted.

To: Hospital Manager

PROTOCOL TITLE

Traditional medicine use in HIV positive patients at Thembaletu Wellness Centre in Northdale Hospital: Prevalence, factors influencing it and its impact adherence to antiretroviral therapy (ART).

Permission is requested to conduct the above research study at the hospital/s indicated below:

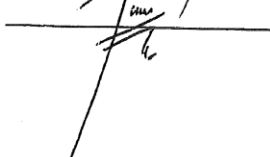
Site address:

Northdale Hospital
P/ Bag X 9006
Pietermaritzburg
3200

Investigator/ s:

Principal: Z.Y.P. Mazibuko

Signature of Hospital Manager:



Date: 2010 / 09 / 08.

NB: Hospital Manager/s to send a copy of this document to Natalia.

Appendix E

Information Document and Informed Consent Form

INFORMATION DOCUMENT

Study title:

Traditional medicine use in patients on antiretroviral therapy (ART): A cross-sectional study at Thembaletu Wellness Centre in Northdale Hospital

Dear Participant

Introduction:

I, Zethu Mazibuko am doing research on the traditional medicine use by HIV-positive people on antiretroviral therapy during 2010. Research is just the process to learn the answer to a question. In this study we want to learn if traditional medicines use has any impact on adherence to ART. This is important to learn because anything that hinders adherence to ART is important to public health. This is a study involving research and not routine care.

Invitation to participate: I am asking / inviting you to participate in a research study.

What is involved in the study – This is a descriptive cross-sectional study design, as a participant you will be requested to complete a questionnaire about the use of traditional medicines. The study is expected to cease on 30/11/2010. A sample of 75 people will take part in the study, and all from South Africa.

No risks are foreseen of being involved in the study.

There are no potential benefits of being in the study.

The participant will be given pertinent and appropriate information on the study while involved in the project and after the results are available.

Participation is entirely voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty loss of benefits to which you are otherwise entitled.

No reimbursements will be provided for participating in this study

Confidentiality: Every effort will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Biomedical Research Ethics Committee, Data Safety Monitoring Committee and the Medicines Control Council.

If results are published, this will not lead to individual identification.

Contact details of researcher/s – **for further information / reporting of study related adverse events.**

Zethu Mazibuko

Cell Number: 0829571712

Contact details of BREC Administrator or Chair – for reporting of complaints/problems:

**Biomedical Research Ethics, Research Office, UKZN, Private Bag X54001,
Durban 4000**

Telephone: +27 (0) 31 260 4769 / 260 1074

Fax: +27 (0) 31 260 4609

Administrator e-mail: BREC@ukzn.ac.za

CONSENT DOCUMENT

Consent to Participate in Research

Dear Participant

My name is Zethu Mazibuko and I am a student at the University of KwaZulu Natal. I am in a process of doing a research about the use of traditional medicines by the people who are taking antiretroviral medicines.

You have been asked to participate in a research study called: Traditional medicine use in patients on antiretroviral therapy (ART): A cross-sectional study at Thembaletu Wellness Centre in Northdale Hospital. Clinic medical records will be used to double check information collected by a questionnaire.

You have been informed about the study by Zethu Mazibuko

You may contact Zethu Mazibuko at 0829571712 any time if you have questions about the research or if you are injured as a result of the research.

You may contact the **Biomedical Research Ethics Office** on **031-260 4769 or 2601074** or Email BREC@ukzn.ac.za if you have questions about your rights as a research participant.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop at any time.

If you agree to participate, you will be given a signed copy of this document and the participant information sheet which is a written summary of the research.

The research study, including the above information, has been described to me orally. I understand what my involvement in the study means and I voluntarily agree to participate. I have been given an opportunity to ask any questions that I might have about participation in the study.

<hr/> Signature of Participant	<hr/> Date
 <hr/> Signature of Witness (Where applicable)	 <hr/> Date
 <hr/> Signature of Translator (Where applicable)	 <hr/> Date